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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,295	04/25/2001	Noel Caplice	07039-175001	7824

26191 7590 11/05/2004

FISH & RICHARDSON P.C.
3300 DAIN RAUSCHER PLAZA
60 SOUTH SIXTH STREET
MINNEAPOLIS, MN 55402

EXAMINER	
NAFF, DAVID M	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 11/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/843,295	CAPLICE ET AL.	
	Examiner	Art Unit	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

An amendment of 8/16/04 amended claims 1, 12 and 32.

Claims examined on the merits are 1-37, which are all claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-26, 28 and 31-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to describe a medical device that is not a stent and is balloon expandable as now claimed. Only a stent is described as being balloon expandable (page 6, lines 13-24). A balloon expandable medical device that is not a stent is an invention not originally described in the specification.

Claim Rejections - 35 USC § 112

Claims 1-26, 28 and 31-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a stent being the medical device that is balloon expandable, does not reasonably provide enablement for another medical device that is balloon expandable. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification (page 6, lines 13-24) enables only a stent as a medical device that is balloon expandable. No other medical device is described that functions by being balloon expandable. It would be uncertain as to another medical device is expanded by a balloon to function as occurs when using a balloon to expand a stent. The claims must be commensurate in scope with the balloon expandable medical device enabled in the specification.

Claim Rejections - 35 USC § 112

Claims 28 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 is confusing and unclear by requiring the medical device to be a vascular graft and depending on claim 12 that requires the device to be balloon expandable. The specification fails to describe

a balloon expandable vascular graft, and it would be uncertain as to structure of a balloon expandable vascular graft.

Claim 29 is confusing as to how it further limits claim 27 by requiring the stent of claim 27 to be balloon expandable since claim 12 on which claim 27 depends requires a medical device that is balloon expandable. Therefore, the stent of claim 27 is required to be balloon expandable in claim 12, and being balloon expandable in claim 29 does not further limit claim 27.

Claim 29 is further confusing by requiring the stent of claim 27 to be self-expanding as an alternative to being balloon expandable. Since claim 12 requires the device to be balloon expandable, this precludes an alterative of self-expanding. A dependent claim cannot add a limitation to a prior claim that is not within the scope of the prior claim.

Claim Rejections - 35 USC § 103

Claims 12, 14-20 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vacanti et al (6,348,069 B1) in view of Healy et al (5,670,161).

The claims are drawn to an implantable medical device comprising cells and a plurality of surfaces, wherein at least one of the surfaces comprises a non-woven framework of fibers having an average size of at least 40 μm, and the device is implantable and balloon expandable within the vascular system of a mammal.

Vacanti et al disclose forming an implantable matrix structure that can be tubular in the form of a blood vessels, intestine, ureters and fallopian tubes (col 7, lines 42-43) and be formed of a fibrous polymeric matrix (col 3, lines 42-43) that can be non-woven (col 3, line 51), have pores of 100-300 microns (col 3, line 57), and be seeded with cells including smooth muscle cells or fibroblasts (col 6, lines 26-31). The polymer can be polyglycolic acid (col 4, line 9) and be coated with a polymer that enhances cell attachment such as fibronectin (col 5, line 25). The matrix structure may also contain growth factors (col 5, lines 59-65).

Healy et al disclose a balloon expandable stent (col 11, lines 38-45 and col 12, lines 46-55) that is non-woven (col 12, line 63) and is formed from fibers (paragraph bridging cols 9 and 10).

It would have been obvious to form the tubular structure containing cells of Vacanti et al as a stent from un-woven fibers as suggested by Healy et al to obtain the function of a stent since a stent is tubular and Vacanti et al suggest forming different tubular structures in general containing cells from un-woven fibers.

Claim Rejections - 35 USC § 103

Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 12, 14-20 and 26-29 above, and further in view of Ferrara et al (6,455,283 B1).

The claims require cells that express a polypeptide such as vascular endothelial growth factor.

Ferrara et al disclose transforming cells to produce vascular endothelial cell growth factor with a nucleic acid encoding the factor.

When producing the structure containing cells of Vacanti et al as a stent from un-woven fibers as set forth above, it would have been obvious to use cells that are encoded to produce a growth factor as taught by Ferrara et al since Vacanti et al disclose providing growth factors in the matrix of the structure (col 5, lines 59-62).

Claim Rejections - 35 USC § 103

Claims 1-7, 9-11, 13, 24, 25 and 30-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 12, 14-20 and 26-29 above, and further in view of Ducheyne (5,030,233) and Cottone Jr (5,824,043).

The claims require the medical device to contain a non-woven framework make of metal fibers, and be balloon expandable.

Ducheyne disclose a porous metal material for surgical implantation made of metal fibers such as stainless steel or titanium (col 12, lines 45-46), and having a pore size of at least 150 micrometers (col 12, lines 49-50). The material is made by sintering fibers together (col 7, lines 25-45). As shown by Figure 1, the material is non-woven.

Cottone Jr discloses an expandable stent (col 3, lines 35 -40) made of metal strands (col 4, lines 1-5 and col 6, lines 12-18) or polymers (col 6, lines 18-21).

When forming the tubular structure of Vacanti et al as a stent from un-woven fibers as set forth above, it would have been obvious to use metal fibers as the fibers as suggested by Ducheyne using metal fibers to form an implant and Cottone Jr using metal stands or polymers to form a stent. Using metal fibers would have been obvious when the properties of metal fibers are desired as compared to properties of fibers made from a polymer.

Claim Rejections - 35 USC § 103

Claims 8 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-7, 9-11, 13, 24, 25 and 30-34 above, and further in view of Ferrara et al ('283).

The claims require cells that express a polypeptide such as vascular endothelial growth factor.

Ferrara et al is described above.

When forming the structure containing cells of Vacanti et al as a stent and using metal fibers as set forth above, it would have been obvious to use cells encoded to produce vascular endothelial growth factor as taught by Ferrara et al since Vacanti et al can have growth factors present in the matrix of the structure (col 5, lines 59-62).

Response to Arguments

In response to the above rejections, applicants urge that Vacanti et al implant the matrix subcutaneously for sufficient time to obtain fibrous tissue or blood vessel ingrowth and remove the matrix for further implanting, and do not teach an implantable medical device

containing cells and a non-woven framework wherein the device is implantable and balloon expandable in the vascular system of a mammal.

However, the present claims do not exclude the claimed medical device being implanted, removed and implanted again as disclosed by Vacanti et al. The claims are drawn to a medical device, and do not limit how the device is used in a method of implantation. The cells in the device claimed can be cells seeded into the matrix of Vacanti et al, or cells contained by tissue infiltrated in the matrix of Vacanti et al after initial implanting.

While the structure of Vacanti et al is not disclosed as being balloon expandable, tubular structures are described including blood vessels and other tubular structures, and the structures are described as formed of multiple fibers in non-woven mesh (col 3, lines 49-51). Since the balloon expandable stent of Healy et al is tubular and can be formed of non-woven fibers and be implanted in a blood vessel, it would have been obvious to form the tubular structure of Vacanti et al as a balloon expandable stent as described by Healy et al when desiring the function of a stent instead of the function of a blood vessel.

Applicants urge that Healy et al or Cottone Jr does not suggest modifying the materials of Vacanti et al to arrive at the claimed invention. However, due to the similarly of the implantable tubular structure of Vacanti et al to the stent structure of Healy et al, it would have been obvious that the tubular structure of Vacanti et al can be formed as a stent to obtain stent function. Explicit

directions are not required to make the modification, it is enough for the invention to be obvious to one of ordinary skill in the art having the references (*In re siebentritt*, 152 USPQ 618).

Cottone Jr is relied on to suggest using metal fibers to prepare the stent and is not applied alone to suggest forming the structure of Vacanti et al as a balloon expandable stent. Since Healy et al and Cottone Jr disclose the stent containing perforations or pores for cell ingrowth, and the similar structure of Vacanti et al contains seeded cells before implanting, it would have been obvious to provide seeded cells in a stent structure formed as the tubular structure of Vacanti et al to obtain the function of the seeded cells before implanting as obtained by Vacanti et al, i.e. to provide cells for growth without having to wait for cell ingrowth after implanting. Healy et al and Cottone Jr are applied together with Vacanti et al, and the invention becomes obvious when the references are considered in combination instead of each alone. Similarly, Ferrara et al and Ducheyne are not applied alone but in combination with other references. The invention of the claims to which these references are applied is obvious when these references are taken in combination with all references applied.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David M. Naff
Primary Examiner
Art Unit 1651

DMN
11/4/04